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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,115	04/12/2006	Jingwu Z. Zang	050989.0202.01USPC	5131

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EXAMINER	
JUEDES, AMY E	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,115	ZANG, JINGWU Z.	
	Examiner	Art Unit	
	AMY E. JUEDES	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,8,11,12,14,16,17,21-23 and 28-33* is/are pending in the application.

4a) Of the above claim(s) *1,3-6,8,11,12,14,21-23 and 30-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,17,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 12/29/08, is acknowledged.

Claims 2, 7, 18-20, and 25 have been cancelled.

Claims 1, 5-6, 8, 11, 16-17, and 22 have been amended.

Claims 28-33 have been added.

Claims 1, 3-6, 8, 11-12, 14, 16-17, 21-23, and 28-33 are pending.

2. Applicant's election with traverse of group II, drawn to a composition comprising cross-reactive T cells, claims 16-17 and newly added claims 28-29, in the reply filed 12/29/08 is acknowledged.

Applicant's traversal is on the grounds that the claims as amended share a special technical feature over the prior art of Cirone et al., since Cirone et al. do not teach T cells that react with residues 93-105 or 96 to 102 of myelin basic protein (MBP) and resides 4-10 or 1-13 of the HHV-6 U24 protein. Claim 16, as amended, is drawn to a T cell that cross-reacts with a self antigen and a foreign antigen, wherein the self-antigen comprises residues 96-102 of MBP, and the foreign antigen comprises residues 4-10 of HHV-6 U24. The claims do not require that the T cells be specific for the 96-102 epitope, but merely that they react with an antigen comprising said epitope. The T cells of Cirone et al. cross-react with a self antigen (full length MPB protein) and a foreign antigen (HHV-6 virus). Since the full length MBP protein comprises residues 96-102, said T cells do react with a self antigen comprising residues 96-102 of MBP, as claimed. Likewise, the entire HHV-6 virus is a foreign antigen that inherently comprises residues 4-10 of the U24 protein, as recited in the instant claims.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 3-6, 8, 11-12, 14, 21-23, and 30-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 16-17 and 28-29 are under examination.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-17 and 28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is indefinite in the recitation of specific amino acid residues of MBP or HHV-6 U24 protein in the absence of a SEQ ID NO. For example, MBP exists in several isoforms with a different number of amino acids, and residues 96-102 would not be the same in all MBP proteins. In the absence of a SEQ ID NO., the metes and bounds of the claim directed to specific residues of a protein cannot be determined.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 16-17 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Cirone et al., 2002 (of record), as evidenced by Janeway and Travers, 1997.

Cirone et al. teach T cell lines (i.e. an enriched composition of T cells) that cross react with full length MBP (i.e. a self antigen) and HHV-6 (i.e. a foreign antigen). Furthermore, the full length MBP protein comprises residues 96-102, and therefore said T cells react with a self antigen comprising residues 96-102 of MBP, as recited in the instant. Likewise, HHV-6 virus is an antigen that comprises residues 4-10 of the U24 protein, as recited in the instant claims. Thus, the T cells of Cirone et al. cross-react with an antigen comprising residues 96-102 of MBP and antigen comprising residues 4-10 of HHV-6 U 24 protein. Additionally, Cirone et al. teach cultures of the cells comprising 2×10^5 cells/0.2 mls (i.e. cells at a concentration of 1×10^6/ml). Cirone et al. teach that the T cells proliferate in response to MBP or HHV-6 antigen. As evidenced by Janeway and Travers, antigen encounter by T cells leading to proliferation results in the

expression of IL-2 and the upregulation of IL-2R (i.e. CD25) by the T cells (see page 7:15 in particular). Therefore, the antigen stimulated T cell lines of Cirone et al. inherently express IL-2R (i.e. CD25) and IL-2.

Thus, the reference clearly anticipates the invention.

6. Claims 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Tejada-Simon et al., 2001, as evidenced by Janeway and Travers, 1997, and Tejada-Simon et al., 2003 (of record).

Tejada-Simon et al. teach T cell lines specific for residues 91-109 of MBP (i.e. an antigen comprising residues 93-105 of MBP). As evidenced by Tejada-Simon et al.(2003), the precursor frequency of T cells specific for the MBP 93-105 epitope that cross-react with residues 1-13 of HHV-6 U24 is greater than 50% (see page 192 in particular). Additionally, said T cells cross-react by recognizing a common epitope that is found in both sequences, and said epitope is part of the 91-109 peptide of Tejada-Simon et al. (see residues 96-102 in Table 2). Tejada-Simon et al. teach generating 30 T cell lines specific for MBP 91-109 peptide (see page 908 in particular). Given the precursor frequency of cross-reactive T cells taught by Tejada-Simon et al. (2003), at least some of said T cell lines would inherently cross-react with residues 1-13 of HHV-6 U24. Additionally, Tejada-Simon et al. teach that the MBP stimulated T cell lines express IL-10, TNF-alpha, IFN-gamma, and IL-4 (see page 910 in particular). Additionally, as evidenced by Janeway and Travers, antigen encounter by T cells leading to proliferation results in the expression of IL-2 and the upregulation of IL-2R (i.e. CD25) by the T cells (see page 7:15 in particular). Therefore, the antigen stimulated T cell lines of Tejada-Simon et al. would inherently express IL-2R (i.e. CD25) and IL-2.

Thus, the reference clearly anticipates the invention.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-17 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cirone et al., 2002 or Tejada-Simon et al., 2001, in view of Zang et. al., 1993 (of record), as evidenced by Tejada-Simon et al. 2003, and Janeway and Travers, 1996.

The teachings of Cirone et al., Tejada-Simon et al., 2001, and the evidentiary teachings of Tejada-Simon et al., 2003 and Janeway and Travers, 1996, are described above.

They do not teach a cell concentration from 2 x 10^6 cells/ml to 9 x 10^7 cells/ml.

Zang et al. teach that MBP reactive T cells are useful for T cell vaccination, and can be administered at a dose 1-15x 10^7 cells per 0.5 mls (i.e. a cell concentration o 20-30 x 10^6 cells/ml, see page 1451 and 1454, in particular).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to prepare the MBP reactive T cells of Cirone et al. or Tejada-Simon et al. at a concentration of 20-30 x 10^6 cells/ml. The ordinary artisan would have been motivated to do so, since Zang et al. teach that said dose of MBP reactive T cells is useful for T cell vaccination.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes whose telephone number is 571-272-4471. The examiner can normally be reached on 7am to 3:30pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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